< Applicant> < Address>

<Postal Code>

< Town>

<Country>

<Date>

<Rwanda FDA>

<P.O.BOX 1948> <Kigali>

< Rwanda >

Dear Sir/Madam,

**Subject: Submission of Application Dossier for Marketing Authorization of <Product Name and strength>**

We are pleased to submit our Application Dossier for a registration of Herbal Medicinal Product that details are as follows:

**Name of the Herbal Medicinal** **product:** ………………………………….…………….

**Dosage form and strength:** …………………………………………….………………...

**Herbal Active ingredient(s):** …………………….............................................................

………….………………………………………………………………………………….

**Manufactured by:** (Manufacturer Name and physical Address**)** ………………………...

You will find enclosed the submission dossier as specified hereafter:

 The relevant fees for this application have been paid.

 CD rom/external driver that contains summaries in word format and body data in searchable



PDF format





We confirm that the electronic submission has been checked with up-to-date and state-of-the-art antivirus software.



 I confirm that the Product Dossier information submitted including composition, formulation, strength, specifications and packaging is the same in all aspects as the products registered with the relevant WLAs, WHO PQ and EAC.

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>